510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
K042472

B. Purpose of Submission:
Clearance of new device

C. Analyte:
Influenza A and B viral antigens

D. Type of Test:
Rapid chromatographic immunoassay that differentiates influenza A viral antigens from influenza B viral antigens

E. Applicant:
Becton, Dickinson and Company

F. Proprietary and Established Names:
BD Directigen™ EZ Flu A+B Kit

G. Regulatory Information:

1. Regulation section:
   21 CFR§866.3330
2. Classification:
   I
3. Product Code:
   GNX – Antigens, CF including CF controls), Influenza Virus A, B, C.
4. Panel:
   83 Microbiology

H. Intended Use:

1. Intended use(s):
   The BD Directigen™ EZ Flu A+B test is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral antigens from nasopharyngeal washes/aspirates and throat swabs of symptomatic patients. The BD Directigen EZ Flu A+B test is a differentiated test, and therefore influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. All negative test results should be confirmed by cell culture.

2. Indication(s) for use:
   The BD Directigen™ EZ Flu A+B test is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral antigens from nasopharyngeal washes/aspirates and throat swabs of symptomatic patients. The BD Directigen EZ Flu A+B test is a differentiated test, and therefore influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections.

3. Special condition for use statement(s):
   For Prescription Use Only

4. Special instrument Requirements:
   Not applicable

I. Device Description:

The BD Directigen™ EZ Flu A+B test is a chromatographic assay to qualitatively detect influenza A and B viral antigens in samples processed from respiratory specimens. When specimens are processed and added to the test device, influenza A and/or B viral antigens bind to anti-influenza antibodies conjugated to visualizing particles in the corresponding A and B test strips. The antigen-conjugate complex migrates across the test strip to the reaction area and is captured by the line of antibody on the membrane. A positive result for influenza A is visualized as a reddish purple line at the Test "T" position and the Control "C" position in the BD Directigen™ EZ Flu A read window and a visible reddish purple line at the Control "C" position in the BD Directigen™ EZ Flu B read window. A positive result for influenza B is visualized as a reddish purple line at the Test "T" position and the Control "C" position in the BD Directigen™ EZ Flu B read window and a visible reddish purple line at the Control "C" position in the BD Directigen™ EZ Flu A read window.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Viral cell culture, direct fluorescent antibody (DFA) tests,
   BD Directigen™ EZ Flu A+B test (K001364),
   and the Remel Xpect FLU A/B test (K031565).

2. Predicate K number(s):
   K001364, K031565,

3. Comparison with predicate(s):

Similarities					
Item	**Device**	**Predicate**	**Predicate**	**Predicate**	**Predicate**
	BD Directigen™ EZ Flu A+B	**Viral Cell Culture**	**Direct Fluorescent Antibody (DFA)**	**BD Directigen™ Flu A+B**	**Remel Xpect™ FLU A/B**
Intended use	an *in vitro* diagnostic product for direct and qualitative detection of influenza A and B viral antigens from nasopharyngeal washes/aspirates and throat/lower nasal swabs	Viral cell culture uses kidney cell lines or other cell lines for the recovery of live influenza A or B viruses from direct specimens of symptomatic patients.	The DFA test is a fluorescent antibody assay for the detection of influenza A and/or B antigens from cell culture or intact epithelial cells from respiratory specimens.	The BD Directigen™ Flu A+B Test is a rapid *in vitro* enzyme immunoassay (EIA) membrane test for the direct and qualitative detection of influenza A and B viral antigens from respiratory specimens listed below. It is not intended for detection of influenza C.	REMEL's Xpect™ FLU A/B is a rapid *in vitro* immunochromatographic test for the direct, qualitative detection of influenza A and influenza B viral antigen (nucleoprotein) from respiratory specimens listed below. It is an aid in the rapid diagnosis of influenza A and influenza B viral infections. Negative tests should be confirmed by cell culture.
Specimen types	nasopharyngeal washes/aspirates, throat/lower nasal swabs	Respiratory tract specimens	Respiratory tract specimens	nasopharyngeal washes/aspirates, nasopharyngeal swabs, lower nasal swabs, throat swabs and bronchoalveolar lavages	nasal washes, nasal swabs and throat swabs
Assay Tech-nology	Immuno-chromatographic	Tissue culture	Microscopic slide immunofluorescence	EIA (enzyme immunoassay) – Flow through capture	Immuno-chromatographic
Detection of Flu A + B viruses	Differentiated influenza A and influenza B	Differentiated influenza A and influenza B	Differentiated influenza A and influenza B	Differentiated influenza A and influenza B	Differentiated influenza A and influenza B

Differences					
Item	**Device**	**Predicate**	**Predicate**	**Predicate**	**Predicate**
	BD Directigen™ EZ Flu A+B	**Viral Cell Culture**	**Direct Fluorescent Antibody (DFA)**	**BD Directigen™ Flu A+B**	**Remel Xpect™ FLU A/B**
Assay Tech-nology	Immuno-chromatographic	Tissue culture	Microscopic slide immunofluorescence	EIA (enzyme immunoassay) – Flow through capture	Immuno-chromatographic
Total assay time	Less than 30 min	Up to 14 days	~ 1-2 hours	Less than 30 min	Less than 30 min
Level of	Moderately complex	Complex	Complex	Moderately complex	Moderately complex

skill					
Limit of detection	**$CEID_{50}$/ml**	Not available	Not available	**$CEID_{50}$/ml**	**$CEID_{50}$/ml**
A/PR/8/34 (H1N1)	1.75×10^4			8.2×10^3	8.9×10^3
A/FM/1/47 (H1N1)	1.98×10^3			5.9×10^2	7.9×10^1
A/NWS/33 (H1N1)	1.00×10^4			1.6×10^2	NA
A1/Denver/1/57 (H1N1)	5.56×10^3			6.5×10^1	NA
A/New Jersey/8/76 (H1N1)	4.45×10^3			2.1×10^2	8.9×10^1
A/Port Chalmers/1/73 (H3N2)	1.00×10^3			2.9×10^2	4.0×10^1
A/Hong Kong/8/68 (H3N2)	2.78×10^2			NA	2.8×10^1
A2/Aichi2/68 (H3N2)	3.50×10^3			NA	NA
A/Victoria/3/75 (H3N2)	2.78×10^4			3.3×10^4	8.9×10^2
B/Lee/40	6.95×10^5			1.2×10^6	7.9×10^3
B/Allen/45	2.00×10^3			1.8×10^2	4
B/GL/1739/54	5.56×10^3			2.5×10^3	8.9×10^1
B/Taiwan/2/62	3.50×10^2			6.6×10^2	3
B/Hong Kong/5/72	2.23×10^4			2.3×10^3	1.58×10^2
Item	**Device**	**Predicate**	**Predicate**	**Predicate**	**Predicate**
	BD Directigen™ EZ Flu A+B	**Viral Cell Culture**	**Direct Fluorescent Antibody (DFA)**	**BD Directigen™ Flu A+B**	**Remel Xpect™ FLU A/B**
Clinical sensitivity/ *Clinical specificity*	Influenza A: Nasal washes/ aspirates (n=466): **85.8% (79.9-91.7%)** *99.4% (97.8-99.9%)* Throat swabs(n=269) **76.8% (63.6-87.0%)** *86.4% (81.6-91.0%)* Influenza B: Nasal washes/ aspirates (n=466) **80.3% (69.1-88.8%)** *99.7% (98.6-100%)* Throat swabs(n=269) **69.1% (55.2-80.9%)** *98.6% (96.0-99.7%)*	Not available	Not available	Influenza A: Nasal aspirates (n = 350): **95.7% (85.2-99.5%)** *91.4% (87.6-94.3%)* Throat swabs(n=389) **76.7% (65.4-85.8%)** *90.8% (87.1-93.8)* Influenza B: Nasal aspirates (n = 350) **87.5% (71.0-96.5%)** *98.1% (95.9-99.3%)* Throat swabs(n=389) **0% (0.0-97.5%)** *100% (99.1-100%)*	Influenza A: Nasal washes/ aspirates (n=239): **92.5% (79.6-98.4%)** *100% (98.2-100%)* Throat swabs (n=30) **100% (69.2-100%)** *100% (83.2-100%)* Influenza B: Nasal washes/ aspirates (n=268) **100% (90.3-100%)** *100% (98.2-100%)* Throat swabs (n=30) **100% (39.8-100%)** *100%(86.8-100%)*

K. Standard/Guidance Document referenced (if applicable):

Not applicable

L. Test Principle:

The device is a chromatographic assay for qualitative influenza A and B viral antigen detection in respiratory specimens. Mucolytic agents (reagent E) breaks down mucous in a patient specimen to expose viral antigens and enhance detection in the assay device. Processed specimens are expressed through a filter tip into each of two sample wells in the device. The applied specimen flows across the device membrane through capillary action for detection of influenza antigens. The influenza A antigen in the specimen binds to anti-influenza A monoclonal antibody conjugated to colloidal gold and the gold complex is captured on the test line ("T") of the reaction strip in the Flu A read window by a second anti-influenza A monoclonal antibody. The influenza B antigen in the specimen binds to anti-influenza B monoclonal antibody conjugated to colloidal gold and is captured on the test line ("T") of the reaction strip in the Flu B read window by a second anti-influenza B monoclonal antibody. Any unbound antibody-colloidal gold complex continues to flow up the reaction strip and is captured by the control line ("C") of the respective reaction strip. The viral antigens detected by device are highly conserved nucleoprotein of the influenza viruses, not hemagglutinin (HA) or neuraminidase (NA) proteins. Therefore, minor point mutations (i.e., antigenic drift) to either one or both of the surface proteins (i.e., HA or NA) should not affect the BD Directigen EZ Flu A+B test.

A **positive** result for **influenza A** is visually interpreted as a **reddish purple line at the test position ("T") and the control position ("C") within the Flu A read window**. A positive result for influenza B is visually interpreted as a reddish purple line at the test position ("T") and the control position ("C") within the Flu B read window. A **negative** result for influenza A and influenza B antigens is visually interpreted as the **absence of a reddish purple line at the "T"** positions **with** the **presence of a reddish purple line at the "C"** positions in both read windows.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The reproducibility of BD Directigen™ EZ Flu A+B assay was determined with a panel of twenty simulated samples (influenza positive and negative). Four clinical trial sites conducted the test. The panel for Influenza A and B had known negative (n=10), low positive (n=4, 2xLoD, and medium positive (n=6, 8xLoD) members. The samples were coded and randomly sorted to prevent their identification during testing. Each site tested the panel on three separate, successive days using two different kit lots of BD Directigen™ EZ Flu A+B. Three of the 4 sites demonstrated 100% reproducibility, one site misidentified one sample on one of the days

resulting in a total reproducibility of 98.3% for that site. The overall reproducibility for all sites was determined as 99.6%.

b. Linearity/assay reportable range:

Not applicable

c. Traceability (controls, calibrators, or method):

Not applicable

d. Detection limit:

The limit of detection (LoD) for each viral strain was defined as the lowest concentration level of the strain that produced a positive reaction with all three replicates of the test using a two-fold dilution serious. Each set of two-fold dilutions (one set per viral strain) was required to contain at least one dilution that resulted in negative results with all three replicates. Additionally each set of serial dilutions was required to contain at least two consecutive dilutions that both resulted in positive results for all three replicates.

The limit of detection (LoD) for the BD Directigen EZ Flu A+B test was established for a total of 15 influenza strains; nine influenza A and six influenza B. The ATCC reported concentration of viral particles of each strain was used to calculate the lowest concentration detectable by the BD Directigen EZ Flu A+B test from the highest dilution that resulted in positive results.

Type	Influenza Viral Strain	LoD ($CEID_{50}$/mL*)
A	A/PR/8/34 (H1N1)	1.75×10^4
A	*A/FM/1/47 (H1N1)*	1.98×10^3
A	A/NWS/33 (H1N1)	1.00×10^4
A	A1/Denver/1/57 (H1N1)	5.56×10^3
A	A/New Jersey/8/76 (H1N1)	4.45×10^3
A	A/Port Chalmers/1/73 (H3N2)	1.00×10^3
A	A/Hong Kong/8/68 (H3N2)	2.78×10^2
A	A2/Aichi2/68 (H3N2)	3.50×10^3
A	A/Victoria/3/75 (H3N2)	2.78×10^4
B	B/Lee/40	6.95×10^5
B	B/Allen/45	2.00×10^3
B	B/GL/1739/54	5.56×10^3
B	B/Taiwan/2/62	3.50×10^2
B	B/Hong Kong/5/72	2.23×10^4
B	B/Hong Kong/5/72	2.23×10^4

***** $CEID_{50}$/mL = Chick Embryo Infectious Dose at which 50% of the embryos perish

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e. Analytical specificity:

Evaluation of media for preservation and transport of respiratory specimens:

Simulated positive samples were prepared by diluting influenza A (Flu A/PR/8/34) or influenza B (Flu B/Lee/40) in each medium to a concentration equivalent to two times the LOD. Two aliquots of each spiked medium (one at room temperature for 1-2 hours and one stored overnight at –20 ± 5 °C) were tested in triplicate devices as processed samples to examine for interference and any effects of storage on performance in the BD Directigen EZ Flu A+B test. Of the 24 media tested in this evaluation, 21 demonstrated the expected results and met the acceptance criteria for both storage conditions. The following media are compatible with the BD Directigen EZ Flu A+B test: Phosphate Buffered Saline (PBS), PBS plus 0.5% gelatin, PBS plus 0.5% BSA, Veal Infusion Broth (VIB), VIB plus 0.5% BSA, Hanks Basal Salt Solution, M4 Media, M5 Media, Bartel ViraTran Media, Sucrose Phosphate (2-SP) , Trypticase Soy Broth, Trypticase Soy Broth plus 0.5% gelatin, Trypticase Soy Broth plus 0.5% BSA, Earle's Minimal Essential Medium (EMEM), EMEM plus 0.5% BSA, EMEM plus 1.0% BSA, Modified Stuarts liquid Culture Swab, Amies (liquid) Culture Swab, M4 RT Media, Starplex Multitrans, Cellmatics.

EMEM plus 0.5% lactalbumin and EMEM plus 1.0% lactalbumin media are not compatible with the device and this will be reflected in the package insert. Regarding normal saline, the data show that this media is not appropriate for the overnight frozen storage of samples. Therefore, frozen storage of specimens collected in normal saline is not recommended for this test.

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Cross reactivity Study:

Dulbecco's phosphate buffered saline (D-PBS) inoculated with the following microbial agents (to a final sample concentration of approximately 1.5 X 10^8 CFU/mL (CFU – Colony Forming Unit) do not react with the BD Directigen EZ Flu A+B test: *Acinetobacter baumannii(calcoaceticus), Actinobacillus suis, Bacteroides fragilis, Bordetella pertussis, Candida albicans, Candida glabrata, Cardiobacterium hominis, Chlamydia trachomatis* LGVII, *Corynebacterium diphtheriae, Corynebacterium diphtheriae, Eikenella corrodens, Enterococcus faecalis, Enterococcus gallinarum, Escherichia coli, Fusobacterium nucleatum, Gardnerella vaginalis, Haemophilus aphrophilus, Haemophilus influenzae, Haemophilus parainfluenzae, Haemophilus paraphrophilus, Kingella kingae, Klebsiella pneumoniae, Lactobacillus casei, Lactobacillus fermentum, Lactobacillus plantarum, Legionella pneumophila, Listeria monocytogenes,*

Moraxella catarrhalis, Mycobacterium avium, Mycobacterium intracellulare, Mycobacterium tuberculosis, Mycoplasma orale, Mycoplasma pneumoniae, Neisseria gonorrhoeae, Neisseria meningitidis, Neisseria mucosa, Neisseria sicca, Neisseria subflava, Peptostreptococcus anaerobius, Porphyromonas asaccharolyticus, Prevotella oralis, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Salmonella choleraesuis sub *Minnesota, Serratia marcescens, Staphylococcus aureus, Staphylococcus aureus*-Cowan 1, *Streptococcus bovis* II Group D, *Staphylococcus epidermidis, Streptococcus mutans, Streptococcus oralis, Streptococcus pneumoniae, Streptococcus pyogenes* Group A, *Streptococcus sanguis, Streptococcus* sp. Group B, *Streptococcus* sp. Group C, *Streptococcus* sp. Group F, *Streptococcus* sp. Group G, *Veillonella parvula.* Relevant concentrations of the following virues do not react with the assay: *Adenovirus, type 3 (GB), Adenovirus, type 5 (Adenoid 75), Adenovirus, type 7 (Gomen), Adenovirus, type 10 (J.J.), Adenovirus, type 18 (D. C.), Coronavirus (229E), Coxsackievirus Type A9 (Griggs), Coxsackievirus Type A9 (P.B. Bozek), Coxsackievirus Type B5 (Faulkner), Coxsackievirus Type B6 (Schmitt), Coxsackievirus Type A21 (Kuykendall), Cytomegalovirus (AD-169), Echovirus Type 2 (Cornelis), Echovirus Type 3 (Morrisey), Echovirus Type 6 (D'Amori), HSV Type 1 (HF), HSV Type 2 (MS), Influenza A/PR/8/34 (H1N1), Influenza A/Victoria/3/75 (H3N2), Influenza B/Hong Kong/5/72, Influenza B /Lee/40, Influenza B/Allen/45, Influenza B/GL/1739/54, Influenza B/Maryland/1/59, Influenza B/Taiwan/2/62, Measles virus (Edmonston), Mumps virus (Enders), Parainfluenza Type 1 (Sendia/52), Parainfluenza Type 2 (Greer), Parainfluenza Type 3 (C243), Rhinovirus Type 1A (2060), Rhinovirus Type 2 (HGP), Rhinovirus Type 13 (353), Rhinovirus Type 15 (1734), Rhinovirus Type 16 (11757), Rhinovirus, Type 37 (151-1), RSV Type A (Long), RSV Type B (Wash/18537/62), VZV (Ellen)*

Interference study:

An interference study was conducted and the following substances were determined to have no effect on test results when present in spiked samples in the concentrations indicated: Whole Blood (2%), Mouthwash (25%, Scope, Listerine, Tom's of Maine), Cough drops (25% Lozenge, Halls, Cold-Eeze, Sucrets), Nasal Spray (10%, Afrin, 4-Way, Giant brand, 4-Acetamidophenol (10 mg/mL), Acetylsalicylic acid (20 mg/mL), Chlorpheniramine maleate (5 mg/mL), Dextromethoraphan (10 mg/mL), Diphenhydramine HCl (5 mg/mL), Pseudoephedrine HCl (20 mg/mL), Guaiacol Glyceryl Ether (20 mg/mL), Ibuprofen (10 mg/mL), Oxymetazoline(0.05 mg/mL), Phenylephrine(1 mg/mL), Loratidine (100 ng/mL),

Fexofenadine (500 ng/mL), Zanamavir (1 mg/mL), Amantadine (500 ng/mL), Rimantadine (500 ng/mL), Albuterol (0.083 mg/mL), Oseltamivir (500 ng/mL), Ribavirin (500 ng/mL), Synagis (0.1 mg/mL.

f. Assay cut-off

Not applicable.

2. Comparison studies:

a. Method comparison with gold standard: see clinical studies

b. Matrix comparison:

Not applicable

3. Clinical studies: General remarks: Performance characteristics for the BD Directigen EZ Flu A+B test were established in a multi-center study conducted at five trial sites during the 2003-2004 respiratory season and 13 trial sites during the 2004-2005 respiratory season. The clinical centers were located in geographically diverse areas within the United States, Japan and Hong Kong. The study consisted of four segments:

a) Proficiency Evaluation,
b) Clinical Specimen Performance,
c) Reproducibility Testing, and
d) Clinical Specimen Stability.

Proficiency and reproducibility were conducted using panels of simulated samples provided by BD. Clinical performance was conducted on surplus prospective and retrospective (frozen) respiratory specimens. Clinical specimen stability testing was conducted using surplus prospective respiratory specimens

a. Proficiency evaluation

Five clinical centers performed testing for the BD Directigen EZ Flu A+B assay. Each clinical site was required to demonstrate at least 90% proficiency with a panel of twenty simulated influenza samples prior to enrolling clinical specimens. The panel included the following samples: influenza A and B positive (both A & B: n = 4 low positive, 2X LoD; n = 4 medium positive, 8X LoD). Eighteen (18) technologists participated in the clinical study. All eighteen of the technologists passed the proficiency panel testing (i.e., demonstrated at least 90% proficiency) for the BD Directigen EZ Flu A+B in their first attempt.

b. Clinical sensitivity:

A total of 735 prospective specimens were evaluated using the BD Directigen EZ Flu A+B test and cell culture. These specimens consisted of nasopharyngeal washes, nasopharyngeal aspirates, and throat swabs from patients suspecting of having influenza.

The performance characteristics for BD Directigen EZ Flu A+B test as compared to cell culture for each specimen type are presented in Tables 1 through 4.

Table 1: Summary of the Performance of the BD Directigen EZ Flu A+B Test Compared to Culture for all Specimen Types -– Influenza A Combined 2003-2004 and 2004-2005 Respiratory Seasons

		Cell Culture	
Specimen Type	**BD Directigen EZ Flu A+B Test**	**P**	**N**
Nasopharyngeal washes/aspirates	**P**	115	02
	N	19	330
Sensitivity: 86% (95% CI: 79% - 91%) Specificity: 99% (95% CI: 98% - 100%)			
Throat/lower nasal swabs	**P**	43	29
	N	13	184
Sensitivity: 77% (95% CI: 64% - 87%) Specificity: 86% (95% CI: 81% - 91%)			

Table 2: Summary of the Performance of the BD Directigen EZ Flu A+B Test Flu A+B Test Compared to Culture for all Specimen Types -– Influenza B Combined 2003-2004 and 2004-2005 Respiratory Seasons

		Cell Culture	
Specimen Type	**BD Directigen EZ Flu A+B Test**	**P**	**N**
Nasopharyngeal wash/aspirates	**P**	57	1
	N	14	394
Sensitivity: 80% (95% CI: 69% - 89%) Specificity: 100% (95% CI: 99% - 100%)			
Throat/lower nasal swabs	**P**	38	3
	N	17	211
Sensitivity: 69% (95% CI: 55% - 81%) Specificity: 99% (95% CI: 96.4% - 100%)			

Table 3: Summary of the Performance of the BD Directigen EZ Flu A+B Test Compared to Culture for all Specimen Types by Population – Influenza A

Combined 2003-2004 and 2004-2005 Respiratory Seasons

		Cell Culture			
Specimen Type	**BD Directigen EZ Flu A+B Test**	**Pediatric**		**Adult**	
		P	**N**	**P**	**N**
Nasopharyngeal washes/aspirates	**P**	94	2	21	0
	N	11	294	8	36
Sensitivity: **Pediatric**: 90% (95% CI: 82% - 95%); **Adult**: 72% (95% CI: 53% - 87%) Specificity: **Pediatric**: 99% (95% CI: 98% - 100%); **Adult**: 100% (95% CI: 90% - 100%)					
Specimen Type	**BD Directigen EZ Flu A+B Test**	**Pediatric**		**Adult**	
		P	**N**	**P**	**N**
Throat swabs	**P**	38	23	5	6
	N	10	151	3	33
Sensitivity: **Pediatric**: 79% (95% CI: 65% - 90%); **Adult**: 63% (95% CI: 24% - 91%) Specificity: **Pediatric**: 87% (95% CI: 81% - 91%); **Adult**: 85% (95% CI: 69% - 94%)					

Table 4: Summary of the Performance of the BD Directigen EZ Flu A+B Test Compared to Culture for all Specimen Types by Population – Influenza B

Combined 2003-2004 and 2004-2005 Respiratory Seasons

		Cell Culture			
Specimen Type	**BD Directigen EZ Flu A+B Test**	**Pediatric**		**Adult**	
		P	**N**	**P**	**N**
Nasopharyngeal washes/aspirates	**P**	49	1	8	0
	N	13	338	1	56
Sensitivity: **Pediatric**: 79% (95% CI: 67% - 88%); **Adult**: 89% (95% CI: 52% - 100%) Specificity: **Pediatric**: 100% (95% CI: 98% - 100%); **Adult**: 100% (95% CI: 94% - 100%)					
Specimen Type	**BD Directigen EZ Flu A+B Test**	**Pediatric**		**Adult**	
		P	**N**	**P**	**N**
Throat swabs	**P**	19	1	19	2
	N	12	190	5	21
Sensitivity: **Pediatric**: 61% (95% CI: 42% - 78%); **Adult**: 79% (95% CI: 58% - 93%) Specificity: **Pediatric**: 99% (95% CI: 97% - 100%); **Adult**: 91% (95% CI: 72% - 99%)					

b. Clinical specificity: *Refer to (a.) above*

c. Other clinical supportive data (when a and b is not applicable)
Clinical Specimens Stability Study:
This study tested the stability of the influenza viruses in clinical specimens under various storage conditions before testing with the BD Directigen™ EZ Flu A+B test. The data generated in this study provides evidence that clinical specimens maintain positivity or negativity in the BD Directigen EZ Flu A+B test for up to 72 hours at 2-8°C or up to one week at –20°C.

4. Clinical cut-off:
Not applicable

5. Expected values/Reference range: (Interpretive Criteria)
Not applicable.

N. The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this Premarket notification is complete and supports a substantial equivalence decision.